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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/921,290	08/03/2001	David M. Goldenberg	329572	5316

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EXAMINER	
HARRIS, ALANA M	

ART UNIT	PAPER NUMBER
1643	

MAIL DATE	DELIVERY MODE
09/11/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	09/921,290	GOLDENBERG, DAVID M.	
	Examiner	Art Unit	
	Alana M. Harris, Ph.D.	1643	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *26 June 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-3,5-10,14-18,25-29,32-37,41-44,46 and 48-50* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-3, 5-10,14-18,25-29,32-37,41-44,46 and 48-50* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Request for Continued Examination

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on June 26, 2007 has been entered.

2. Claims 1-3, 5-10, 14-18, 25-29, 32-37, 41-44, 46 and 48-50 are pending.

Claims 1, 9, 10, 16, 18, 25-27, 34 and 44 have been amended.

Claims 11-13, 19-24, 30, 31, 38-40, 45 and 47 have been cancelled.

Claims 49 and 50 have been added.

Claims 1-3, 5-10, 14-18, 25-29, 32-37, 41-44, 46 and 48-50 are examined on the merits.

Withdrawn Rejections

Claim Rejections - 35 USC § 112

3. The rejection of claims 16-18 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention has been withdrawn in light of the amendment to the claims. Claims 19, 39 and 40 have been cancelled.

Claim Rejections - 35 USC § 103

4. The rejection of claims 1-5, 7-9, 15-18, 25-29, 32-35, 37, 41-44 and 46 under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent number 5,776,456 (filed June 7, 1995), and in view of U.S. Patent number 5,837,242 (May 14, 1996) and Rybak et al. (Proc. Nat. Acad. Sci. USA 89: 3165-3169, April 1992) is withdrawn in light of Applicant's amendment to claim 1. Claims 11, 12, 19-24, 38-40 and 45 have been cancelled.

5. The rejection of claims 1-10, 14-18, 25-27, 31, 34-37, 41-44, 46 and 48 under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent number 5,776,456 (filed June 7, 1995), and in view of U.S. Patent 6,217,869 (filed September 5, 1997) is withdrawn in light of Applicant's amendment to claim 1. Claims 11-13, 19-24, 38-40, 45 and 47 have been cancelled.

6. The rejection of claims 1, 2, 8, 9, 16, 26 and 44 under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent number 5,776,456 (filed June 7, 1995), and in view of Javid et al. (J. Clin Invest. 31(6): 604-10, June 1952) is withdrawn in light of the claim amendment to claim 1. Claims 11, 12, 19-24 and 30 have been cancelled.

New Grounds of Rejection

Claim Rejections - 35 USC § 102

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

8. Claims 1-3, 5-10, 14-18, 25-29, 32-37, 41-44 and 48-50 are rejected under 35 U.S.C. 102(e) as being anticipated by U.S. Patent Application Publication number 2004/0219203 A1 (effective filing May 10, 1999). The publication discloses methods for treating B-cell malignancies and autoimmune, as well as indolent forms of B-cell lymphomas with a therapeutic composition comprising a pharmaceutically acceptable carrier and an anti-CD74 binding molecule and in combination with antibodies reactive with CD20, as well as HLA-DR, see page 3, sections 0021-0024; page 13, sections 0120 and 0121; section 0122 bridging pages 13 and 14; page 14, section 0126; page 15, sections 0130 and 0131. The publication discloses implementing the method to companion animals, such as a cat or dog, see page 5, section 0049. It is within the purview of the Examiner the disclosed veterinary applications are applicable to additional companion animals, such as those listed in claim 1.

The anti-CD74 binding molecule may include a fusion protein, hybrid molecule and designed to be multispecific, bispecific and bind to a hapten, see page 3, section

0021; page 6, section 0058; page 9, section 0078-0081; page 15, section 0129. The disclosed therapeutic composition includes an effector molecule, such as a drug, toxin (i.e. RNase), cytokine, immunosuppressive agent (i.e. 6-mercaptopurine and prednisone) and radioisotope, see page 2, sections 0007 and 0012; page 4, section 0032; and page 6, section 0057.

9. Claims 1-3, 5, 8-10, 15-18, 25, 26, 32, 33, 37, 41-43, 46 and 48 are rejected under 35 U.S.C. 102(e) as being anticipated by U.S. Patent Application Publication number 2001/0018041 A1 (filed April 16, 2001). The publication discloses methods of treating humans, as well as dogs, casts, horses, cows, pigs, goats, sheep and ungulates (i.e. llamas and alpacas) having CD40+ malignancies, B-cell lymphomas and leukemias with compositions comprising anti-CD20 antibodies (including bispecific antibodies), chemotherapeutic agents, immunosuppressive agents, such as prednisone and radiotherapy, see abstract; page 3, sections 0027 and 0033; section 0082 bridging pages 7 and 8; page 8, section 0091; page 9, section 0092; page 10, sections 0104-0106. The therapeutic composition also comprises a combination of two or more naked antibodies against different epitopes and a fusion protein of antibody combinations, see page 3, sections 0018 and 0027; and page 10, section 0104.

Claim Rejections - 35 USC § 103

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

11. Claims 1-3, 5-10, 14-18, 25-29, 32-37, 41-44 and 48-50 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent Application Publication number 2001/0018041 A1 (filed April 16, 2001), and further in view of U.S. Patent Application Publication number 2004/0219203 A1 (effective filing May 10, 1999). The teachings of publication '8041 have been presented in the 102(e) rejection cited in section number 9. This publication does not teach a method for treating B cell in a companion animal, wherein a therapeutic composition comprises anti-CD74, anti-HLA-DR, or an immunoconjugate comprising a drug or toxin, such as RNase. This publication also does not teach the said method comprising a cytokine or an arm specific for a low-molecular weight hapten. Nor does this publication teach the said method wherein the therapeutic composition comprises a hybrid antibody, anti-CD74 or HLA-DR antibodies.

However, U.S. Patent Application Publication number 2004/0219203 A1 teaches the claimed method, wherein a therapeutic composition comprising a pharmaceutically acceptable carrier and an anti-CD74 binding molecule and in combination with antibodies reactive with HLA-DR for veterinary applications, see page 3, sections 0021-0024; page 13, sections 0120 and 0121; section 0122 bridging pages 13 and 14; page 14, section 0126; page 15, sections 0130 and 0131. Publication '9203 also teaches an

anti-CD74 binding molecule may include a fusion protein, hybrid molecule and designed to be multispecific, bispecific and bind to a hapten, see page 3, section 0021; page 6, section 0058; page 9, section 0078-0081; page 15, section 0129. The disclosed therapeutic composition includes an effector molecule, such as a drug, toxin (i.e. RNase), cytokine, immunosuppressive agent (i.e. 6-mercaptopurine and prednisone) and radioisotope, see page 2, sections 0007 and 0012; page 4, section 0032; and page 6, section 0057. It would have been *prima facie* obvious to one of ordinary skill in the art at the time the claimed invention was made to utilize the different combinations of the therapeutic compositions for treatment of B-cell lymphomas and leukemias. One of ordinary skill in the art would have been motivated to manufacture such a medicament in order to effectively treat companion animals/domestic animals because both publications set forth treatment of B cell malignancies targeting the CD20, CD74 and HLA-DR antigens, see both publications in their entireties.

12. Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Alana M. Harris, Ph.D. whose telephone number is (571)272-0831. The Examiner works a flexible schedule, however she can normally be reached between the hours of 7:30 am to 6:30 pm, with alternate Fridays off.

If attempts to reach the Examiner by telephone are unsuccessful, the examiner's supervisor, Larry R. Helms, Ph.D. can be reached on (571) 272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

ALANA M. HARRIS, PH.D.
PRIMARY EXAMINER

Alana M. Harris, Ph.D.
31 August 2007